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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,493	06/19/2001	Vincent Bryan	46739/252170	5642

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HAYNES AND BOONE, LLP  
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EXAMINER

STEWART, ALVIN J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/744,493

Applicant(s)

BRYAN ET AL.

Examiner

Alvin J Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 8, 10-13 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3738

***Response to Arguments***

Applicant's arguments, see paper # 16, filed June 12, 2003, with respect to the rejection(s) of claim(s) 1-13 and 15-21 under Graf US Patent 6,419,706 B1 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al US Patent 5,545,229.

Parsons et al discloses an intervertebral disc comprising an upper half (8), a lower half housing (10) and a plurality of separate, resilient discs (2 & 4) interposed between the housing halves.

The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). In the Merriam-Webster Dictionary the word "separate" means the following: "to make a distinction between; isolate from mixture; divide into constitute parts". Therefore, the two structure elements 2 and 4 can be interpreted as separate structures.

Art Unit: 3738

Claims 11, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Cauthen US Patent 6,019,792.

Cauthen discloses an intervertebral implant comprising two separate halves (10 & 40), at least one prosthetic disc (90) located between the two housing halves, threaded exterior surface (80) and a plurality of recesses (62 & 72). It is an inherent characteristic of surgical procedures to insert more than one implant if the replacement of two or more natural discs are required.

Claims 11, 12, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Rogozinski US Patent 5,888,226.

Rogozinski discloses an intervertebral implant comprising a disc (10 & 20) having viscoelastic properties (hydrogel, see col. 3, lines 52-54), the implant having convex external surfaces (see Fig. 9). Finally, the disc has relatively soft and resilient interior (10) and a relatively hard exterior (20).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al US Patent 5,545,229 in view of Cauthen US Patent 6,019,792.

Parsons et al discloses the invention substantially as claimed. However, Parsons et al does not disclose a continuous thread formation at the exterior surface of the housing of the implant.

Art Unit: 3738

Cauthen teaches an implant having a housing with a threaded surface for the purpose of facilitating the advance of the implant into the vertebral space during implantation and to help secure the implant in position when implanted (see col. 6, lines 26-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer circumference of the housing of the Parsons et al reference with the outer circumference of the Cauthen reference in order to facilitate advancing of the implant into the vertebral space during implantation and to help secure the implant in position when implanted.

Claims 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski US Patent 5,888,226 in view of Cauthen US patent 6,019,792.

Rogozinski discloses the invention substantially as claimed. However, Rogozinski does not disclose a continuous thread formation at the exterior surface of the housing of the implant.

Cauthen teaches an implant having a housing with a threaded surface for the purpose of facilitating the advance of the implant into the vertebral space during implantation and to help secure the implant in position when implanted (see col. 6, lines 26-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer circumference of the housing of the Rogozinski reference with the outer circumference of the Cauthen reference in order to facilitate advancing of the implant into the vertebral space during implantation and to help secure the implant in position when implanted.

Regarding claim 21, Figures 2-12 disclose a plurality of nuclei of different sizes.

Art Unit: 3738

Note: If the Applicant wants to claim more than one resilient disc, the Applicant has to enter more limitations describing that the discs are interposed between the parts.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski US Patent 5,888,226 in view of Cauthen US patent 6,019,792 as applied to claim 18 above, and further in view of Bryan et al US Patent 5,674,296.

Rogozinski in view of Cauthen discloses the invention substantially as claimed. However, Rogozinski in view of Cauthen do not disclose a flexible sheath or seal.

Bryan et al teaches an intervertebral disc comprising two halves, a resilient disc and a flexible sheath or seal covering for the purpose of rendering the flexible sheet material substantially impervious to the passage of any fluid (see col. 4, lines 47-49).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add to the Rogozinski et al reference the sheath discloses in the Bryan et al reference (as discloses by the applicant in page 5, first paragraph) in order to render the flexible sheet material substantially impervious to the passage of any fluid.

***Allowable Subject Matter***

Claims 1-7 are allowed.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

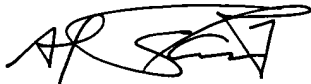
Art Unit: 3738

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'A. Stewart', with a stylized flourish at the end.

Alvin Stewart  
December 11, 2003.